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510(k) Summary for the
Lutronic Corporation Spectra DENTA II/Spectra SP II Laser Systems

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

AUG 19 2009

1. General Information

Submitter:

Lutronic Corporation
#403-2,3,4, Ilsan Technotown
1141-1 Baeksok-Dong, Ilsan-Gu
Goyang-Si, Gyeonggi-Do, 410-722
Republic of Korea

Contact Person:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
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Summary Preparation Date:

April 29, 2009

2. Names

Device Name:

Spectra DENTA II Laser System
Spectra SP II Laser System

Classification Name:

Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Devices

The Spectra DENTA II and Spectra SP II Laser Systems are substantially equivalent to a combination of the Lutronic Corporation Spectra SP Laser System (K050254), the Lumenis Family of UltraPulse SurgiTouch CO2 Laser Systems (K030147), the Lumenis Compact 30C CO2 Lasers (K935563 and K963229), the MedArt Uni-Laser 450P CO2 Laser System & Accessories (K991297), the OpusDent Ltd. Opus Duo EC (K021508) and the Cynosure Smart US 20 D / UltraSpeed, and Smart Clinic Laser (K081181).

4. Device Description

The Spectra DENTA II and Spectra SP II Laser Systems are identical CO2 laser systems supplied with different handpieces depending upon the indications for use. They consist of a self-contained console, an articulated arm delivery system, a footswitch and a pair of goggles. The Spectra DENTA II and Spectra SP II Laser Systems produce a beam of coherent infrared (10.6μm) light and have Continuous Wave, Char-Free and Super Pulse operation modes.

The main console is the heart of the Spectra DENTA II and Spectra SP II Laser Systems and contain the optical system (with DC-Excited Sealed-off Carbon Dioxide gas tube), cooling system, arm mount, micro-controller, and power supply. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the control panel. There are 4 casters in the console base for moving the system.

The laser beam exits an articulated arm into a handpiece where it is focused by the final focus lens contained in the handpiece to produce a spot size at the treatment focal plane. The handpiece components, when inserted in the beam delivery system, change the laser beam characteristics. Different handpieces are provided with the Spectra DENTA II and the Spectra SP II depending upon the desired indications for use.

5. Indications for Use

The Spectra DENTA II Laser System is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.

The Spectra SP II Laser System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Treatment of wrinkles, rhytids and furrows
- Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology, Plastic Surgery & General Surgery

Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for

hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

Gynecology
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

6. Performance Data
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Lutronic Corporation
% O'Connell Regulatory Consultants
Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

AUG 19 2009

Re: K091320
Trade/Device Name: Spectra DENTRA II Laser System
Spectra SP II Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 3, 2009
Received: July 6, 2009

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Deputy Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091320

Device Name: Spectra DENTA II Laser System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use (Per 21 CFR 801.109)

OR

Over The Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091320

Indications for Use

510(k) Number (if known): K091320

Device Name: Spectra SP II Laser System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use (Per 21 CFR 801.109) OR Over The Counter Use (Optional Format 1-2-96)

Neil R Ogden for mkm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091320

K091320

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use (Per 21 CFR 801.109)	OR	Over The Counter Use (Optional Format 1-2-96)

Michael Ryan for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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